

IN THE UNITED STATES PATENT OFFICE

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Application Serial No. 10/020,881

**CUSTOMER NO. 23607**

Our Ref.: PT1950001

Applicant: Dialysis Solutions Inc.

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**RECEIVED**

APR 17 2002  
TECHNOLOGY CENTER R3700

Title: STERILE BICARBONATE-FREE DIALYSIS  
CONCENTRATE SOLUTIONS

Inventors: Sheldon Tobe

**Due Date:** April 19, 2002

**INFORMATION DISCLOSURE STATEMENT**

April 15, 2002

The Commissioner of Patents  
UNITED STATES PATENT OFFICE  
2011 South Clark Place  
Crystal Plaza 2, Room 1B03  
Arlington, Virginia U.S.A. 22202

Dear Sir:

Applicants and the undersigned are aware of "patents, publications, or other information" which they believe may be material to the examination of the above-identified application. Copies of these items, and one sheet of Form PTO-1449 listing them, are submitted herewith pursuant to 37 C.F.R. §§ 1.97-1.99 and to the duty of disclosure set forth in 37. C.F.R. § 1.56.

As Applicant has not received an Office Action from the United States Patent Office with regard to this application, Applicant believes that no fee is required in accordance with 37 CFR §1.97. However, if a fee is required for the filing of this information disclosure statement, please obtain such fee from Deposit Account 08-3255 and advise Applicant's Agent.

Although this Information Disclosure Statement identifies references which may be "material," it is not intended to constitute an admission that any patent, publication, or other information referred to is "prior art" (within the meaning of 35 U.S.C. §102 and §103) as to the invention disclosed and claimed in this application unless specifically designated as such. Moreover, no representation is intended as to the relative relevance of any portion of the references or as to the relevance among references, whether cited in this Statement or elsewhere.

In accordance with 37 C.F.R. §1.97(b), the filing of this Information Disclosure Statement shall not be construed to mean that a novelty search has been made or that no other information which may be material (as defined in 37 C.F.R. §1.56(a)) exists.

**UNITED STATES PATENT DOCUMENTS**

U.S. Patent No. 5,211,643 to Reinhardt et al

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

Yatzidis et al., "Hemodialysis with a New Single Stable Bicarbonate Dialysate", Nephron, Vol. 64, 1993; 27-31

F. H. Leenen, et al., "Hemodynamic Changes During Acetate and Bicarbonate Hemodialysis", Artificial Organs 8(4), 1984; 411-417

M. Kaye et al., "Calcium-free Dialyzate: Development and Applications", Clinical Nephrology, Vol. 31, No. 3, 1989; 132-138

M. Kaye and D. Fisher, "Changes in Intact Parathyroid Hormone Levels During Hemodialysis Following Exposure to Either Differing Dialyzate Calcium Concentrations or Calcium-Free Dialysis with Varying Calcium Infusion Rates"  
Clinical Nephrology, Vol. 34, No. 2, 1990; 84-87

M. Kaye, "Long-term studies using a calcium-free dialysate",  
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P.Y.W. Tam et al., "Slow Continuous Hemodialysis for the Management of Complicated Acute Renal Failure in an Intensive Care Unit",  
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E.F.H. Van Bommel et al, "Acute Dialytic Support for the Critically III: Intermittent Hemodialysis Versus Continuous Arteriovenous Hemodiafiltration",  
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Nephrol Dial. Transplant 1995 Editorial Comments, p. 311

A. Davenport et al., "Hyperlactataemia and Metabolic Acidosis During Haemofiltration Using Lactate-Buffered Fluids", Nephron, Vol. 59, 1991; 461-465

M. Leblanc et al., "Bicarbonate Dialysate for Continuous Renal Replacement Therapy in Intensive Care Unit Patients With Acute Renal Failure",  
Am. J. Kidney Diseases, Vol. 26, No. 6, 1995; 910-917

Knaus W.A. et al., "APACHE II: A Severity of Disease Classification System",  
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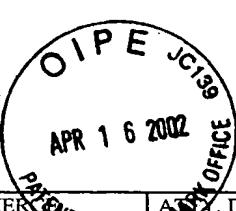
Jordan, D.A. et al., "Evaluation of Sepsis in a Critically ill Surgical Population",  
Critical Care Med., Vol. 15, No. 10, 1987; 897-904

Respectfully submitted

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Agent for Applicant

NHH:mse  
Enclosures

# CITATION OF PRIOR ART



Sheet 1 of 1

FORM PT0-1449 (REV. 8-83)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 1950001	APPLICATION SERIAL NO. 10/020,881
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)		APPLICANT DIALYSIS SOLUTIONS INC.	
CUSTOMER NO. 23607		FILING DATE 12/19/2001	GROUP ART UNIT 3762

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,211,643	05/18/93	Reinhardt et al	604	416	05/25/90

## FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES      NO

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Yatzidis et al., "Hemodialysis with a New Single Stable Bicarbonate Dialysate", Nephron, Vol. 64, 1993; 27-31	APR 17 2002
	F. H. Leenen, et al., "Hemodynamic Changes During Acetate and Bicarbonate Hemodialysis", Artificial Organs 8(4), 1984; 411-417	TECHNOLOGY CENTER R3700
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	Jordan, D.A. et al., "Evaluation of Sepsis in a Critically ill Surgical Population", Critical Care Med., Vol. 15, No. 10, 1987; 897-904	
EXAMINER	DATE CONSIDERED	

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.